



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/528,417

07/26/2006

Martinus Antonius Wiegerinck

0470-050863

2537

28289 7590 12/08/2009
THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,417	Applicant(s) WIEGERINCK ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,23-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,23-29 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 25 is objected to because of the following informalities: The liquid containing means having a volume of less than 10cc is not disclosed in the specification. However, Claim 25 was submitted in a preliminary amendment at the time of the filing of the application, and is therefore being treated as part of the original specification. The Applicants may amend the claim to claim the currently disclosed subject matter, or the Applicants may amend the specification to state the liquid containing means has a volume of less than 10cc. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20, 23-28, 31, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) in view of Mendoza et al (6,071,231) in view of Suzuki et al (4,781,699).

Ayre discloses a cytological sampling instrument and further discloses a tubular means for insertion into a body cavity (Figure 1; and Abstract), the tubular means (5) has a curved distal end (head 7 has a rounded end, see Figure 1), a storage means (7) connected to the tubular means (5) and a vacuum means (6) connected to the storage means (7) and tubular means (5), the tubular means (5) has a diameter of at least 1cm

Art Unit: 3736

and has openings (11) only at the curved distal end (see Column 3, lines 7-12; bulb 6 provides vacuum when the bulb is depressed (evacuated) and the external pressure is released); a liquid containing means and pump means for expelling the liquid at the distal end of the device (head 7 contains a charge of a glycerine compound, wherein the glycerine is expelled when bulb 6 is depressed); the storage means (7) comprise the liquid containing means; the liquid means has a volume of less than 10cc (the very distal portion of storage means 7 would contain less than 10cc); a sealing means (12) for sealing the openings; the liquid containing means contains a flushing solution (the glycerine solution acts as a flushing solution when expelled from the device when placed at the cervix); the flushing solution is expelled from the device and a sample is introduced in the device. See Column 3, lines 7-10, 17-21, 38-45 and 65-68; and Column 4, lines 7-12 and 38-41.

Ayre and Suzuki et al however fail to disclose the rigid tube provides a closure in the body cavity for a flushing solution when expelled; and the tube further comprises a number of sampling openings only at the curved introduction end, wherein the number of sampling openings comprises a central opening.

Mendoza et al disclose a means for artificial insemination and further disclose the rigid tube provides a closure (24) in the body cavity for a flushing solution when expelled; and the tube further comprises a number of sampling openings (27) only at the curved introduction end (at 22 in Figure 4), wherein the number of sampling openings comprises a central opening (see Figures 4 and 5).

Art Unit: 3736

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include a closure in the body cavity when the flushing fluid is expelled, and a number of sampling openings around a central opening, as per the teachings of Mendoza et al, since it would provide a means of preventing the tube from dislodging from the location during flushing, as well as concentrating all of the flushing and sampling at the very distal end of the device.

Ayre and Mendoza et al however fail to disclose openings that are less than 5mm in diameter; the vacuum means comprise a pump means; the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder.

Suzuki et al disclose a mucus sampling device and further disclose openings that are less than 5mm in diameter (see Column 2, lines 64-65); the vacuum means comprise a pump means (the plunger acts as a pump); the vacuum means comprise a plunger-cylinder (4, 6); and the tube (2) comprises the cylinder. See also Column 2, lines 20-23, 38-44, 64 and 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Mendoza et al to include the use of small diameter openings as well as a different type of a vacuum source, as per the teachings of Suzuki et al, since it would provide a device that has the ability to obtain a mucus sample utilizing a vacuum source.

4. Claims 29, 30, 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432), Mendoza et al (6,071,231) and Suzuki et al

Art Unit: 3736

(4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Lurie et al (7,207,951 B1).

Ayre, Mendoza et al and Suzuki et al, as discussed above, disclose a cervical mucus sampling means, but fail to disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline.

Lurie et al, as discussed above, disclose a means for obtaining cell samples and further disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means (10) for the plunger; and the flushing solution comprises physiological saline (Column 4, lines 63-65). See Column 4, lines 2-11; Column 5, lines 44-67; and Column 6, lines 1-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre, Mendoza et al and Suzuki et al to include a means of biasing the plunger and utilizing saline as the flush solution, as per the teachings of Lurie et al, since it is well known in the art to utilize a biasing means on the plunger as well as utilizing saline as a flush solution during a medical procedure.

5. Claims 33, 34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432), Mendoza et al (6,071,231) and Suzuki et al (4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Oster (3,815,580).

Art Unit: 3736

Ayre, Mendoza et al and Suzuki et al, as discussed above, disclose a means of obtaining a mucus sample, but fail to disclose a kit comprising a closable container for containing the sample, and the container is separate from the sampler; transferring the sample to a container; and the container is provided with a preserving agent.

Oster discloses a means of preserving cytological samples and further discloses a kit comprising a closable container for containing the sample, and the container is separate from the sampler; transferring the sample to a container; and the container is provided with a preserving agent. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre, Mendoza et al and Suzuki et al to include a kit with a closable container for containing the sample, as per the teachings of Oster, since it is well known in the art to obtain a cell sample and place the sample within a fixative for shipping to a lab.

Response to Arguments

6. Applicant's arguments filed August 17, 2009 have been fully considered but they are not persuasive.

The Applicants argue none of the prior art references used in the rejection teach a flushing solution or the expelling step, as currently claimed. The Examiner respectfully disagrees. As stated above, Ayre discloses the claimed flushing solution as being the glycerine chemical complex (see Column 3, lines 38-45). The glycerine complex is placed within the head of the instrument as a charge (a quantity that an apparatus is

Art Unit: 3736

intended to receive and fitted to hold, as defined by Merriam-Webster's Dictionary, 10th Edition). The charge of glycerine acts as a flushing solution, since the charge is expelled from the head 7 during the compression of the bulb 6. The glycerine, once expelled, acts as a means to flush the cell sample from the ribs 10, such that the sample can be acquired once the instrument is withdrawn from the vagina (see Column 3, lines 65-75 and Column 4, lines 1-8). Therefore Ayre clearly discloses the claimed flushing solution and the claimed expelling step.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ayre teaches the use of an instrument for obtaining cervical cells samples through the use of a glycerine solution expelled from the distal end of the instrument through an opening via a compressible bulb, and withdrawal of the device facilitates the vacuum force created during compression of the bulb to draw in the glycerine solution with the cervical cell sample. Mendoza et al disclose a plurality of openings at the rounded distal end and a means for providing a closure in the body cavity for the flushing solution. Suzuki et al disclose a mucus removing device and further disclose the size of the openings and the type of vacuum.

Art Unit: 3736

In response to applicant's argument that Suzuki et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Suzuki et al teach a mucus removal device for removing mucus from the uterocervical canal, wherein the mucus also comprises cells. Per the definition of mucus, as provided by Encyclopedia Britannica, mucus also contains cells. Therefore, not only does Suzuki et al provide a means of removing mucus from the vaginal canal, but the removal of mucus also provides a cell sample. Therefore the prior art Suzuki et al is within the field of Applicants' endeavor.

7. In response to applicant's argument that Mendoza et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Mendoza et al teaches the use of a plurality of openings at the rounded distal end of an instrument for the injection of a fluid, and further teaches a closure means for providing a closure in the female reproductive system when a flushing fluid is expelled.

The Applicants then state the submitted declaration also provides evidence to overcome the prior art rejection. As can be seen below, the submitted declaration is insufficient to overcome the prior art rejection.

The Applicants then argue the prior art of Lurie et al, such that the device of Lurie et al takes samples from the uterus, not the vaginal cavity, and the construction of the devices are different. Therefore one of ordinary skill in the art would not find it obvious to use a vacuum means for retrieving samples from the uterus in a sampler for retrieving a sample from the cervix. The Examiner respectfully disagrees. The placement and use of the device of Lurie et al would not prevent the vacuum source of Lurie et al from being used in any other application, let alone in an application for sampling from the cervix. The vacuum source of Lurie et al creates a vacuum, to draw in a cell sample. One of ordinary skill in the art would be capable of utilizing the vacuum source of Lurie et al to draw in a cell sample from the cervix, or any other internal organ.

Response to Amendment

8. The declaration under 37 CFR 1.132 filed August 17, 2009 is insufficient to overcome the rejection of claims 20, 23-28, 31, 35 and 36 based upon Ayre et al in view of Mendoza et al in view of Suzuki et al as set forth in the last Office action because:

The submitted declaration was one of the Applicants' own inventors. The declaration clearly states the claimed sampler was invented by Wiegerinck himself, but there are two other inventors listed as being co-inventors. Furthermore, Wiegerinck, as being one of the inventors, has a financial stake in the current invention. The inventor

Art Unit: 3736

has also not provided any factual evidence to support the stated assertions within the declaration. Therefore the declaration is being treated as an opinion of one of the current inventors.

The declaration states a long felt need exists "to enable to collect samples in a non-medical surrounding". The Applicant(s) are not claiming a sampler for non-medical surroundings (home use). The claims are drawn only to a sampler. The Applicant(s) have not provided any evidence showing how other inventors have tried but failed to solve the problem. The Applicant(s) have also not provided any evidence with respect to articles, publications or other declarations by one of ordinary skill in the art to show a long felt need. See *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983).

The declaration also states the claimed sampler provides an unexpected result, i.e. to make a sampler that can be used in a non-medical environment. The Applicant(s) have also not provided any evidence in the form of a direct comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims.

The declaration also states the inventor is "aware of the documents cited by the Examiner". The declaration does not state the inventor has read and understood the prior art, and has read and understood the prior art rejection. The inventor has then performed a piecemeal analysis of each of the individual prior art references, instead of the prior art references as combined in the rejection. The inventor also states none of the references disclose a sampler for home use. As stated above, the current claims do not claim a sampler for home use, but do claim a general sampler.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736